

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

3B MEDICAL, INC.,

Plaintiff,

v.

SOCLEAN, INC.,

Defendant.

No. 1:19-cv-03545

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff 3B Medical, Inc. (“3B”) alleges as follows against Defendant SoClean, Inc. (“SoClean”):

NATURE OF THE ACTION

1. This is an action for false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a) and for related violations of New York state law.

2. 3B and SoClean are competitors in the market for devices used to clean continuous positive airway pressure (“CPAP”) machines, which treat sleep apnea. Since approximately 2012, SoClean has used false and misleading representations about its devices to market the SoClean 2 CPAP Sanitizing Machine, the SoClean 2 Go CPAP Sanitizing machine, and their predecessor devices (collectively “the SoClean devices”). The SoClean devices work by generating ozone to sterilize and deodorize CPAP machines. Ozone (O₃) is an unstable toxic gas with a pungent characteristic odor—sometimes described as “clean” smelling—that can kill bacteria and viruses. To be effective as a germicide, ozone must be present in a concentration far greater than can be safely tolerated by people or animals.

3. SoClean’s marketing materials fail to disclose that its devices emit ozone, which is

a longstanding requirement of federal law. Instead, SoClean falsely represents that its devices use “activated oxygen” to clean CPAP machines. SoClean markets the devices as “safe” and “healthy,” which is false given that they generate toxic ozone gas at levels that substantially exceed federal regulations. SoClean falsely represents that its devices use “no water or chemicals” or “no harsh chemicals” to clean CPAP machines, despite using ozone gas—a harsh chemical that causes respiratory problems in humans. SoClean represents that its devices use the same sanitizing process found in “hospital sanitizing,” however, hospitals cannot and do not use ozone sanitizers in spaces occupied by patients. SoClean also claims that separately sold filters convert “activated oxygen” into “regular oxygen,” which is false because SoClean’s filters have no measurable effect on the device’s ozone output. Finally, SoClean falsely claims that its devices are “sealed” such that “activated oxygen” (*i.e.*, ozone) does not escape the devices.

4. SoClean’s misrepresentations have allowed it to command ninety-percent of the relevant market. Due to the nature of SoClean’s business, its customers all have breathing problems for which they are receiving medical treatment in the form of CPAP therapy. If CPAP users knew that the SoClean devices generate unsafe levels of toxic gas, which is then pumped into their CPAP machines and into their bedrooms, they would find this risk material to their purchasing decisions.

5. SoClean’s representations are designed to mislead consumers into believing that the machine uses a benign form of oxygen to clean CPAP machines rather than a harsh gas that is generally only suitable for commercial sanitization under highly controlled conditions. These misrepresentations are made more egregious because the SoClean devices are designed and marketed for use on the consumer’s bedside table and because CPAP users suffer from many symptoms that ozone exposure exacerbates—making the falsehoods especially reprehensible and

dangerous.

PARTIES

6. Plaintiff 3B Medical, Inc. is a Florida corporation with its principal place of business in Winter Haven, Florida.

7. Defendant SoClean Inc. is a Delaware corporation with its principle place of business at 12 Vose Farm Road, Peterborough, New Hampshire 03458.

JURISDICTION & VENUE

8. Subject Matter Jurisdiction. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the Lanham Act, 15 U.S.C. § 1121. The Court also has supplemental jurisdiction over 3B's state law claims pursuant to 28 U.S.C. § 1367(a). In addition, the Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because the amount in controversy exceeds \$75,000 and 3B and SoClean are citizens of different states—Florida and New Hampshire, respectively.

9. Personal Jurisdiction. The Court has personal jurisdiction over SoClean because SoClean regularly conducts business in New York State and because SoClean has falsely advertised the product to the 19.5 million consumers who reside in New York State, including the 5.2 million consumers who reside in the Southern District of New York. SoClean has also sold its products in New York State, including in the Southern District of New York. In addition, SoClean committed tortious acts in New York State, including in the Sothern District of New York, and 3B's claims arise out of such acts, and/or because SoClean has otherwise made or established contacts in New York State, including the Southern District of New York, sufficient to permit the exercise of personal jurisdiction.

10. Venue. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because SoClean is subject to personal jurisdiction in this judicial district and because a substantial part of

the events giving rise to the claims in this action occurred in this judicial district. Specifically, SoClean runs television, online, radio, and print advertising campaigns to promote its products, which reach the more than 5.2 million consumers who reside in the Southern District of New York.

FACTUAL ALLEGATIONS

11. SoClean manufactures and sells medical devices that clean continuous positive airway pressure (“CPAP”) machines.

12. 3B sells a competing device under the brand name “Lumin,” as part of its suite of products for people who suffer from sleep apnea.

A. The Market for CPAP Sanitizing Devices

13. The SoClean and Lumin devices are compatible with many brands of CPAP machines.

14. An estimated 8 million people in the United States use a CPAP machine.

15. A large percentage of CPAP users also suffer from respiratory illnesses.

16. CPAP machines are most commonly prescribed for sleep apnea, a potentially serious disorder in which an individual’s breathing repeatedly stops and starts while sleeping. The most common form of sleep apnea is caused by airway obstruction.

17. CPAP machines are also used to treat diseases such as pulmonary fibrosis and Chronic Obstructive Pulmonary Disease (“COPD”), an umbrella term used to describe progressive lung diseases characterized by increasing breathlessness.

18. While sleeping, a CPAP user wears a face mask, which is attached by a hose to a machine that pressurizes air.



19. Room air is drawn into the CPAP machine through an air intake and, once inside, the machine pressurizes the air. *See* Ex. A (Airflow Diagrams), Figure 1.

20. The pressurized air is then pumped from the CPAP's air outtake, through a hose, and into the facemask, delivering just enough air pressure to keep the user's upper airway passages open while sleeping. *See* Ex. A (Airflow Diagrams), Figure 1.

21. Some CPAP machines also include a heated humidifier that is either fully integrated into the machine or easily attached. Use of the humidifier is optional; generally, it can either be turned off or detached.

22. Many CPAP users concerned with health and cleanliness are interested in regularly sanitizing or disinfecting their CPAP equipment.

23. 3B meets this need through the Lumin, which uses a unique light—a UV-C light source—that has been proven to kill harmful bacteria, viruses, mold, and fungus. *See* Ex. B (Lumin Device Photos).

24. SoClean has taken a different approach to the problem—the SoClean devices use ozone gas in an attempt to clean CPAP equipment.

25. The SoClean 2 and the SoClean 2 Go work similarly, but the SoClean 2 Go is a smaller, more portable version. *Compare* Ex. C (SoClean 2 Photos), *with* Ex. D (SoClean 2 Go Photos).

26. The SoClean devices are Class I medical devices subject to the Medical Device Amendments to the Food, Drug and Cosmetic Act (“FDCA”) and the implementing regulations promulgated by the Food and Drug Administration (“FDA”).

27. As Class I medical devices, the SoClean devices are not subject to premarket review by the FDA.

B. FDA Regulation of Ozone

28. All medical devices must comply with the FDA’s Maximum Acceptable Level of Ozone Rule, 21 C.F.R. § 801.415 (2019).

29. The FDA’s Maximum Acceptable Level of Ozone requirements took effect in 1974. *See* FDA Final Rulemaking: Ozone Generators and Other Devices Generating Ozone, 39 Fed. Reg. 13773-74 (Apr. 17, 1974).

30. The FDA has determined that “[o]zone is a toxic gas.” 21 C.F.R. § 801.415(a).

31. The FDA initially regulated ozone in medical devices because “[i]n order for it to be effective as a germicide, ozone must be present in a concentration far greater than that which can be safely tolerated by man and animals.” FDA Notice of Proposed Rulemaking, 37 Fed. Reg. 12644 (June 27, 1972); *accord* 21 C.F.R. § 801.415(a) (same).

32. The FDA found that “in tests conducted to study the bactericidal properties of ozone, test animals have died before the bacteria were completely destroyed.” FDA Notice of Proposed Rulemaking, 37 Fed. Reg. 12644 (June 27, 1972).

33. The FDA has determined that ozone exposure causes “undesirable physiological effects on the central nervous system, heart, and vision” and “the predominant physiological effect

of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema.” 21 C.F.R. § 801.415(b).

34. FDA regulations make it illegal for a medical device to “generate[] ozone at a level in excess of 0.05 part per million by volume of air circulating through the device” 21 C.F.R. § 801.415(c)(1).

35. FDA regulations make it illegal for a medical device to “cause[] an accumulation of ozone in excess of 0.05 part per million by volume of air . . . in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices.” 21 C.F.R. § 801.415(c)(1).

36. FDA regulations make it illegal for a medical device to “generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm.” 21 C.F.R. § 801.415(c)(2).

37. FDA regulations make it illegal for a medical device “[t]o generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed 0.05 part per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of 0.05 part per million.” 21 C.F.R. § 801.415(c)(3).

C. Ozone Gas

38. Ozone (O₃) is an unstable blue gas with a pungent characteristic odor.

39. Ozone gas forms when oxygen molecules (O₂) interact with electricity and recombine with oxygen atoms (O) to form ozone (O₃).¹

¹ Oxygen atoms (the “O” on the periodic table of elements) and oxygen molecules (the O₂ that we breathe) are both commonly called oxygen.

40. Because ozone is an unstable gas, over time it gradually breaks down by re-combining with other molecules to re-form oxygen (O₂).

41. In still air at room temperature, studies show it can take up to twenty-five hours for ozone levels to reduce by half,² and ozone continues to break down at this rate until it dissipates.

42. When ozone encounters organic material, its third oxygen atom can detach from the ozone molecule and re-attach to molecules of the other substance, thereby altering the chemical composition of the other substance.

43. This reaction, called oxidation, can kill bacteria, viruses, and odors.

44. In sufficiently large quantities, ozone is also toxic to human beings.

45. In smaller quantities, breathing ozone for even a short time can cause adverse health consequences in human beings.

46. Ozone inhalation predominantly affects the respiratory system, and can cause irritation, pulmonary edema, and reduced lung function.

47. Breathing ozone can cause cough and shortness of breath.

48. Breathing ozone can compromise the body's ability to fight respiratory infections.

49. Breathing ozone can worsen asthma symptoms.

50. Breathing ozone can worsen symptoms in people with heart disease.

51. Ozone can react with other chemicals in the air to produce additional chemicals and fine particles that can also be irritating to the eyes, nose, throat, and lungs.

D. SoClean's CPAP Sanitizing Process

52. The SoClean devices sanitize CPAP machines by generating ozone and circulating

² J.D. McClurkin & D.E. Maier, Half-Life Time of Ozone as a Function of Air Conditions and Movement, Presentation at the 10th Int'l Working Conf. on Stored Product Protection (2010), <http://works.bepress.com/dirk-maier/44/> (finding that ozone's half-life varies based on atmospheric conditions with a maximum half-life of 1,524 minutes (25 hours) in dry still cool air).

it throughout the user's CPAP equipment.

53. The SoClean devices work on a variety of different CPAP models and can be used on CPAPs with or without humidifiers.

54. Each SoClean device features an ozone generator, a black hose with a connector, and a chamber. *See* Ex. C (SoClean 2 Photos), Figure 1; Ex. D (SoClean 2 Go Photos), Figure 1.

55. The SoClean 2 has a hard-plastic box as the chamber. *See* Ex. C (SoClean 2 Photos), Figures 1-2.

56. Inside the SoClean 2's chamber, there is a spot for a filter cartridge. *See* Ex. C (Photos of SoClean 2 Device), Figure 1.

57. The SoClean 2 Go uses a cloth bag with a draw string as the chamber. *See* Ex. D (SoClean 2 Go Photos), Figures 1, 4.

58. On the SoClean 2 Go's cloth chamber, there is an outside pocket for a filter cartridge. *See* Ex. D (Photos of SoClean 2 Go Device), Figure 4.

59. The approximately 3.5" long and 1" square filter cartridges consist of a plastic shell filled with granulated charcoal.

60. SoClean makes and markets replacement filter cartridges to SoClean owners and represents that the filter must be replaced every six months for the life of the machine.

61. To set up a SoClean device initially, a user connects the black hose to his CPAP tank's air output opening, where the face-mask hose also attaches. *See* Ex. C (SoClean 2 Photos), Figure 3; *See* Ex. D (SoClean 2 Go Photos), Figure 2.

62. Connecting the black hose sometimes requires an adapter specific to the user's CPAP model.

63. Once connected, the black hose remains attached to the user's CPAP even while

the SoClean device is not in use.

64. SoClean recommends that its customers run at least one cleaning cycle every day.

65. During a cleaning cycle, the SoClean device actively generates ozone for approximately 7 to 14 minutes.

66. To run a cleaning cycle, the user places his face mask into the SoClean device's chamber and closes the lid or draw string. *See* Ex. C (SoClean 2 Photos), Figure 2; Ex. D (SoClean 2 Go Photos), Figure 1.

67. The user can then manually initiate a cleaning cycle by pressing a button or series of buttons.

68. Alternatively, the SoClean 2 automatically runs a cleaning cycle every day when its digital clock reads 10:00 AM.

69. When a cleaning cycle starts, the SoClean device begins generating a large quantity of ozone gas that travels through the black hose into the CPAP's tank.

70. From the CPAP's tank, some of the ozone travels to the face mask and accumulates inside the SoClean device's chamber.

71. By design, this process inundates the CPAP mask, hose, and tank with ozone, killing bacteria, viruses, and odors found within.

72. During a cleaning cycle, the SoClean 2 consistently generates 30 ppm of ozone by volume of air circulating through the device. *See* Ex. E (SoClean 2 Lab Reports) at 1.

73. And within a SoClean device's chamber, 140 ppm of ozone accumulates during a cleaning cycle.

74. During and after a cleaning cycle, ozone escapes a SoClean device in two ways.

75. First, ozone is pumped into the user's CPAP machine and, because CPAP machines

are not airtight, that ozone vents into the user's bedroom.

76. This occurs because a CPAP machine has an open air path between its air intake (where room air enters the machine to be pressurized) and its air outlet (where the face mask and the SoClean device connect to the machine). *See* Ex. A (Airflow Diagrams), Figure 1.

77. Accordingly, ozone that enters the CPAP's air outlet (where the SoClean and face mask attach) can freely escape through the CPAP's air-intake opening. *See* Ex. A (Airflow Diagrams), Figure 2.

78. Anyone in proximity to the device can then inhale the escaped ozone.

79. SoClean users generally keep their SoClean devices attached to their CPAP machines in the bedroom on a bedside table, as consistently depicted SoClean in marketing materials. *See, e.g.*, Ex. G (SoClean Marketing Materials), Figures 1-2.

80. When a SoClean 2 is run for 12 minutes, 28 ppm of ozone escapes the device and accumulates in a 50-liter Teflon chamber—with or without a filter cartridge installed. *See* Ex. E (SoClean 2 Lab Reports) at 2-3.

81. This is 560 times the FDA's limit on ozone generation and accumulation by medical devices. *See* 21 C.F.R. § 801.415(c)(1).

82. When a SoClean 2 Go is run for 10 minutes, 5.6 ppm of ozone escapes the device and accumulates in a 27-liter glass chamber—with or without a filter cartridge installed. *See* Ex. F (SoClean 2 Go Lab Report).

83. This is 112 times the FDA's limit on ozone generation and accumulation by medical devices. *See* 21 C.F.R. § 801.415(c)(1).

84. Second, ozone remains in the CPAP mask, hose, and tank after a cleaning cycle.

85. During normal CPAP use, the user inhales this leftover ozone through the face mask

as air from the CPAP machine flows into the mask.

86. SoClean does not advise users of the risk posed by remaining ozone.

87. Buried in the user guides, SoClean advises users to leave the mask in the SoClean device for two hours to “to achieve maximum sanitizing,” SoClean 2 Go User Guide at 12, or so that “all disinfecting is complete,” SoClean 2 User Guide at 16.

88. The SoClean 2 Go User Guide never warns that the two-hour post-cycle waiting period is intended to avoid exposure to unsafe levels of toxic gas. The SoClean 2 User Guide, in an unrelated FAQ on page 18, states: “The activated oxygen disinfects your equipment and naturally breaks down to regular oxygen within two hours.” However, the SoClean 2 User Guide never links the waiting period is intended or required to allow toxic gas to dissipate.

89. But the ozone within the CPAP mask, hose, and tank does not breakdown within two hours.

90. During testing, ozone levels remain at 3 ppm two hours after a SoClean’s cleaning cycle was complete. *See* Ex. E (SoClean 2 Lab Reports) at 4.

91. When using their CPAP after a cleaning cycle, users often complain of a strong odor.

92. The odor is attributable to ozone gas that remains in the CPAP mask, hose, and tank.

93. The FDA’s MAUDE database, where consumers can report adverse experiences with medical devices, contains the following consumer complaints about SoClean, which are attributable to the adverse effects of unwitting ozone exposure:

- a. “I purchased a soclean c-pap-cleaner. I followed all of the directions i.E., preached the unit, hoses etc. I then cleaned the cpap machine using soclean at the recommended settings. That evening i slept with the cleaned machine. The smell of ozone was strong. The mfr calls ozone activated oxygen. After about

6 hours, i experienced a severe asthma attack which i have never had before. Treatment with rescue inhaler, steroids, bronchodilators. I have cough predominant asthma. The coughing was so severe that i injured my back.”³

- b. “Purchased a soclean 2 cpap sanitizer from apria direct health care. Upon using machine a strong odor was noted on mask, but was told this was normal and that it was like the ocean smell. After the first week i began having trouble with my breathing. It continued to get worse. Started breathing treatments and prednisone did not help. I then found out that they used ozone to sanitize the cpap machine. Checked the (b)(6) clinic web site only to find ozone is an irritant and can cause asthma attacks. Called apira direct and they told me to return the machine. They do not advise you of this danger. I ended up in an urgent care center today for the asthma attack.”⁴
- c. “After approximately 3 months of using soclean 2 cpap cleaner i noticed i was getting sick, started having chest pains for short periods of time each day and felt tired all the time. After research of the product, found it uses ozone to disinfect and found i had most of the symptoms of excess ozone in my system. After 3 days of not using it i am feeling much better with no instances of chest pain and my cold is going away along with my lungs clearing up. I will be seeing my doctor in 2 weeks to be referred to a cardiologist for assessment.”⁵
- d. “I used the soclean cpap cleaning machine, after i purchased it for (b)(6). It used ozone to cleanse cpap machine. There was ozone residue left in my cpap after using the soclean, and that ozone residue burned my sinuses and lungs. This product is hazardous to people’s respiratory systems and it causes pain. It caused me severe pain. This product is unregulated and it should be regulated. I went to the doctor and was told to discontinue use of the soclean machine.”⁶
- e. “I purchased a soclean2 pap disinfecting device on (b)(6) 2018, from (b)(6) center in (b)(6), to clean my cpap unit. Since using the product from that time, i have noticed my sense of taste and smell have diminished dramatically as well as a very dry and an unusual taste in my mouth. Everything i eat tastes bland. Can you tell me if this product has side effects that are causing me these issues? i have not changed anything else in my diet. Including no new medications. Is there residue left from the cleaning that are irritating my mucous membranes?

³ MAUDE Adverse Event Report: Inceptus SoClean 2, FDA (Sept. 10, 2016), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=5969746&pc=LRJ.

⁴ MAUDE Adverse Event Report: SoClean2 CPAP Sanitizer, FDA (Mar. 12, 2018), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7472673&pc=LRJ.

⁵ MAUDE Adverse Event Report: SoClean Inc. SoClean Disinfectant, Medical Devices, FDA (Mar. 12, 2018), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7352173&pc=LRJ.

⁶ MAUDE Adverse Event Report: SoClean Inc. SoClean CPAP Cleaning Machine Disinfectant, Medical Devices, FDA (May 1, 2017), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=7805317&pc=LRJ.

i have appointments to see a pulmonary and nose/throat specialist as well as my dentist to rule out any other medical issues. As i mentioned before, there have been no changes to my diet or lifestyle and current blood tests show no issues.”⁷

94. These experiences are representative of consumers’ experiences with ozone exposure through the SoClean devices.

95. Similar consumer complaints can be found across the internet.

E. SoClean’s False and Misleading Representations

96. SoClean has made material misrepresentations about the SoClean devices’ ozone output across many forums, which are not only false but dangerous for consumers.

1. SoClean’s Failure to Disclose Its Ozone Generation and Use of the Term “Activated Oxygen”

97. The SoClean devices’ packaging does not disclose that the SoClean devices generate ozone or the levels of ozone generated.

98. Marketing materials for the SoClean devices do not disclose that they generate ozone or the levels of ozone generated.

99. Instead, SoClean represents to consumers that it uses “activated oxygen” to sanitize CPAP machines.

100. These omissions and representations are false and misleading.

101. The SoClean devices use ozone to sanitize CPAP machines.

102. As the EPA explains: “Manufacturers and vendors of ozone devices often use misleading terms to describe ozone,” similar to activated oxygen, that “suggest that ozone is a healthy kind of oxygen.” *Ozone Generators that are Sold as Air Cleaners*, EPA (Nov. 27, 2018), <https://www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners#pubs>.

⁷ MAUDE Adverse Event Report: SoClean, Inc SoClean2 CPAP Sanitizing Machine Disinfectant Medical Devices, FDA (Feb. 20, 2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8377760&pc=LRJ.

103. However, “[o]zone is a toxic gas with vastly different chemical and toxicological properties from oxygen.” *Id.*

104. SoClean has represented across many forums that the SoClean devices use “activated oxygen.” For example:

- a. The product packaging for the SoClean 2 never mentions ozone and the box states: “Activated Oxygen powers through your CPAP reservoir, hose, and mask.” *See* Ex. H (SoClean 2 Packaging), Figure 6.
- b. SoClean’s website homepage does not mention ozone and but states: “SoClean’s activated oxygen cleaning completely sanitizes your CPAP mask, hose, and reservoir without any water or chemicals.”⁸
- c. Since at least 2015, SoClean has used a promotional brochure advertising the SoClean devices that does not mention ozone and states: “SoClean’s activated oxygen completely sanitizes your mask, hose, and reservoir without any water or chemicals.”
- d. SoClean’s Amazon Store page for the SoClean devices states: “The SoClean CPAP Cleaner and Sanitizer uses activated oxygen to eliminate any germs and bacteria that may be lingering in your CPAP equipment. SHOP NOW.”⁹
- e. The SoClean 2 Amazon product page maintained by the company fails to disclose that the SoClean 2 generates ozone and states: “The SoClean CPAP sanitizing

⁸ SOCLEAN, www.SoClean.com (last visited Apr. 10, 2019).

⁹ *SoClean: SoClean Devices*, AMAZON, https://www.amazon.com/stores/page/D8D76027-78E7-4B7F-A322-5AB89F68D8DD?ingress=2&visitId=3506ddf6-f414-45c1-8960-17464efa2c52&ref_=bl_dp_s_web_9315360011 (last visited Apr. 20, 2019).

Amazon Store content is created by the brand itself. *See Stores*, AMAZON, <https://advertising.amazon.com/products/stores> (last visited Apr. 20, 2019).

machine uses safe, natural, activated oxygen to thoroughly sanitize and disinfect your entire CPAP system.¹⁰

- f. On the SoClean Website, in answer to the FAQ “Why do I smell ozone in my mask at night when the unit ran in the morning?” SoClean falsely states: “What you smell is not ozone; the equipment is being oxidized with activated oxygen, and that is what you smell – it is completely safe. Some suggestions to lessen the smell: 1) Make sure you use the neutralizing pre-wash. 2) Increase the cleaning time to 12 minutes for a few weeks, then decrease to 7 minutes. 3) Blow air from your CPAP through your mask for 5 minutes before using it. 4) Do not use fragrance wipes or any fragrance products to clean you CPAP equipment, as this will intensify the smell.”¹¹
- g. The 2014 and 2017 online versions of the SoClean 2 User Guide never mentions ozone and state that SoClean disinfects with “activated oxygen.”¹²
- h. The online version of the SoClean 2 Go User Guide never mentions ozone and states: “The SoClean 2 Go uses no fluids in its operation. It sanitizes with activated oxygen. No fluids or water are used in this process.”¹³

105. Buried deep within SoClean’s website are a user-support FAQ page and a “white paper” that disclose that “activated oxygen” is, in actuality, ozone.

¹⁰ *SoClean 2 + Respiroics DreamStation and System One Adapter (SoClean 2 CPAP Cleaner and Sanitizer Bundle with Free Adapter) by SoClean, AMAZON, https://www.amazon.com/dp/B00JWVV4VW/ref=cm_sw_r_sms_awdb_t1_6D0UCbTKP73ZT (last visited Apr. 20, 2019).*

¹¹ *SoClean and Activated Oxygen FAQs*, SOCLEAN, <https://www.soclean.com/sleep-talk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 16, 2019).

¹² *2017 SoClean 2 User Guide*, SOCLEAN, https://www.soclean.com/wp-content/uploads/2017/03/soclean2_manual_RevH.pdf.

¹³ *SoClean 2 Go User Guide*, SOCLEAN, https://www.soclean.com/wp-content/uploads/2014/10/soclean2Go_manual_revA.pdf.

106. The Brochure states: “The SoClean uses ozone – also known as O₃ or activated oxygen – to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today’s world, it’s a trusted sanitizing process used by hospitals, food handlers and the hotel industry.”

107. The FAQ titled “What Is Activated Oxygen” states:

Activated oxygen also known as ozone, or O₃ is defined by Merriam-Webster dictionary as: 1. a form of oxygen that is found in a layer high in the earth’s atmosphere. 2. fresh healthy air especially near the sea. Activated oxygen is a three atom oxygen molecule.

This three atom molecule is a colorless gas with powerful oxidizing properties, formed from oxygen by electrical discharges or ultraviolet light. It differs from normal oxygen (O₂) but over time or with forced filtration, will break back down to normal oxygen (O₂) that we breathe.

Many become confused over the term ozone. There is good ozone and there is bad ozone. Most commonly used is bad ozone which is linked to high ozone alerts or smog alerts in certain areas of the world. This kind of ozone is mixed with toxic gases that can be breathed in. Good ozone is found in our upper atmosphere or you may smell the essence of ozone after a thunderstorm. Activated oxygen (ozone) is known as one of the best and most effective means to natural disinfection. This process is commonly used in array of applications such as public water filtration, fruit and vegetable handling, hotel housekeeping, and hospital disinfection. Please see common FAQs to learn more about activated oxygen (ozone) or see activated oxygen in SoClean to learn how the SoClean safely disinfects your CPAP equipment.”¹⁴

108. Not only are the foregoing disclosures obscure and difficult to locate, but they are themselves affirmatively false and misleading.

109. The disclosures do nothing to cure SoClean’s falsehoods.

2. Representations that the SoClean Devices Use “No Chemicals” and/or “No Harsh Chemicals”

110. SoClean falsely represents that its devices use “no water or chemicals” or “no harsh

¹⁴ *What is activated oxygen?*, SOCLEAN, <https://www.soclean.com/sleep-talk/documentation/activated-oxygen/>.

chemicals” to clean CPAP machines.

111. These representations are false and misleading.

112. The SoClean devices use ozone gas to clean CPAP machines.

113. Ozone is a chemical.

114. Ozone is a harsh chemical.

115. SoClean has repeatedly represented that its devices use “[n]o water or chemicals”

or “no harsh chemicals” to clean CPAP machines across many forums. For example:

- a. The box for the SoClean 2 states: “No water or chemicals.” Ex. H (SoClean 2 Packaging), Figure 3.
- b. Since at least March 28, 2016, SoClean’s website homepage has read: “SoClean kills 99.9% of CPAP germs and bacteria in your mask, hose and reservoir with no disassembly, no water, and no chemicals in order to enhance your home CPAP experience.”¹⁵
- c. SoClean has aired the television commercial “Getting Sick from a Dirty CPAP” at least 10,929 times nationwide since 2018, representing that the SoClean devices use “no harsh chemicals” to clean CPAP machines.
- d. SoClean has aired the television commercial “CPAP Cleaner and Sanitizer” at least 22,058 times nationwide since 2016, representing that the SoClean devices use “no chemicals” to clean CPAP machines.
- e. SoClean has aired the television commercial “Safely Sanitize and Disinfect” at least 6,325 times nationwide between 2017 and July 2018, representing that the SoClean devices use “no harsh chemicals” to clean CPAP machines.

¹⁵ SoCLEAN, www.SoClean.com (last visited Apr. 10, 2019).

- f. SoClean has aired the television commercial “Automated CPAP Sanitizer” at least 512 times nationwide in 2018, representing that the SoClean devices use “no harsh chemicals” to clean CPAP machines.

3. Representations that the SoClean Devices Are “Safe” and “Healthy” for Use

- 116. SoClean often markets its device as “safe” and “healthy.”
- 117. These representations are false and misleading.
- 118. A device that releases toxic gas into a user’s bedroom at levels exceeding federal regulations is not “safe” or “healthy.”
- 119. SoClean has repeatedly represented that its devices are safe and healthy across many forums. For example:
 - a. The packaging for the SoClean 2 states: “Breathe Healthy, Breathe SoClean.” *See* Ex. H (SoClean 2 Packaging), Figure 4.
 - b. Since at least March 28, 2016, SoClean’s website homepage has represented that the SoClean devices offer “Safer, healthier CPAP cleaning.”¹⁶
 - c. A brochure advertising the SoClean and SoClean 2 Go used since at least 2015 reads: “The SoClean makes it easy for any CPAP user to safely and naturally clean and sanitize their equipment on a daily basis.”
 - d. A brochure advertising the SoClean and SoClean 2 Go used since at least 2015 reads: “Featuring the same safe, effective sanitizing process as the SoClean, the SoClean 2 Go is the perfect travel companion for any CPAP user – so small it can fit easily anywhere.”

¹⁶ SOCLEAN, www.SoClean.com (last visited Apr. 17, 2019).

- e. SoClean has aired the television commercial “Getting Sick from a Dirty CPAP” at least 10,929 times nationwide since 2018, representing that the SoClean devices help users stay healthy.
- f. SoClean has aired the television commercial “CPAP Cleaner and Sanitizer” at least 22,058 times nationwide since 2016, representing that the SoClean devices improve users’ health.
- g. SoClean has aired the television commercial “Safely Sanitize and Disinfect” at least 6,325 times nationwide between 2017 and July 2018, representing that the SoClean devices safely sanitize CPAP masks and hoses.
- h. In a brochure that consumers can obtain from SoClean only if they provide a name and valid email address, SoClean states that: “The SoClean uses ozone – also known as O₃ or activated oxygen – to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today’s world, it’s a trusted sanitizing process used by hospitals, food handlers and the hotel industry.”
- i. An Amazon product page maintained by the company reads: “The SoClean CPAP sanitizing machine uses safe, natural, activated oxygen to thoroughly sanitize and disinfect your entire CPAP system.”¹⁷
- j. A SoClean FAQ page represents that: “What is the concentration of ozone inside

¹⁷ *SoClean 2 + Respironics DreamStation and System One Adapter (SoClean 2 CPAP Cleaner and Sanitizer Bundle with Free Adapter) by SoClean, AMAZON, https://www.amazon.com/dp/B00FKBU0X6/ref=sspa_dk_detail_1?psc=1&pd_rd_i=B00FKBU0X6&pd_rd_w=9S2ks&pf_rd_p=80559f3c-f83b-49c1-8a72-40f936e9df7a&pd_rd_wg=4ucG4&pf_rd_r=BAAXN03P5HSPQ64V7BWZ&pd_rd_r=238c6796-5fee-11e9-97cc-7fd3667cd97a&smid=AC3UW2IWHXI2H (last visited Apr. 15, 2019).*

the SoClean CPAP cleaner and sanitizer? SoClean uses enough ozone to thoroughly sanitize your CPAP equipment and by the time you open the chamber it will have decreased to 0 ppm.”¹⁸

4. Representations that the SoClean Devices Use the Same Sanitizing Process Used in Hospitals

120. SoClean represents that its devices use the same sanitizing process found in hospital sanitizing.

121. This representation is false and misleading.

122. Hospital ozone decontamination systems can only be used in vacant, sealed rooms.

123. Hospitals cannot and do not use ozone sanitizers in spaces occupied by patients.

124. SoClean devices, however, are marketed for use in the home, specifically bedrooms, and marketing materials often depict the SoClean device on the user’s nightstand.

125. SoClean has repeatedly represented that its devices are used in hospital sanitizing across many forums. For example:

- a. Since at least 2015, SoClean has used a promotional brochure advertising the SoClean devices that includes:



- b. Since at least 2015, SoClean has used a “rack card” advertising the SoClean devices

¹⁸ *SoClean and Activated Oxygen FAQs*, SOCLEAN, <https://www.soclean.com/sleep-talk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 16, 2019).

that includes:



- a. The box for the SoClean 2 features a similar image that states: “SoClean uses the same sanitizing process found in:” “water,” “produce,” “hotels,” and “hospitals.” See Ex. H (SoClean 2 Packaging), Figure 5.
- b. The SoClean 2 Amazon product page maintained by the company reads “Activated oxygen[.] SoClean uses the same safe and proven sanitizing and disinfecting process found in water purification, produce handling, hotel housekeeping and hospital sanitizing.”¹⁹
- c. In a brochure that SoClean requires consumers to provide a name and valid email address to obtain, SoClean states that: “The SoClean uses ozone – also known as O₃ or activated oxygen – to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today’s world, it’s a trusted sanitizing process used by hospitals, food handlers and the hotel industry.”

5. The Charcoal Filter Cartridges

126. SoClean represents that the filter cartridges convert “activated oxygen” back into

¹⁹ *SoClean 2 + Respirationics DreamStation and System One Adapter (SoClean 2 CPAP Cleaner and Sanitizer Bundle with Free Adapter)* by SoClean, AMAZON, https://www.amazon.com/dp/B00FKBU0X6/ref=cm_sw_r_sms_c_api_i_PCIVCb62EDG8E (last visited Apr. 21, 2019).

“normal oxygen.”

127. This representation is false and misleading.

128. The FDA has determined that there is no reliable way to guarantee the rapid breakdown of ozone to prevent its accumulation in enclosed spaces. *See* FDA Final Ozone Rulemaking, 39 Fed. Reg. 13773, ¶ 6 (Apr. 17, 1974).

129. The filter does not prevent the SoClean devices from emitting ozone into the environment.

130. The SoClean filter does not prevent ozone from escaping into the atmosphere.

131. The SoClean filter has no measurable effect on ozone accumulation.

132. SoClean has repeatedly represented across many forums that its filters convert “activated oxygen” into “regular oxygen.” For example:

- a. The SoClean webpage selling replacement filters states that “[t]he Cartridge Filter converts activated oxygen back to regular oxygen as it leaves the SoClean 2 chamber.”²⁰
- b. The 2017 online version of the SoClean 2 User Guide states: “Additionally, any excess activated oxygen passes through a filter which converts it back to regular oxygen before release.”²¹
- c. The online version of the SoClean 2 Go User Guide states: “This filter converts activated oxygen back into normal oxygen. Replace every 6 months.”²²

²⁰ *Cartridge Filter Kit – SoClean 2*, SOCLEAN, <https://www.soclean.com/product/cartridge-filter-kit-soclean-2/> (last visited Apr. 15, 2019).

²¹ *2017 SoClean 2 User Guide*, SOCLEAN, https://www.soclean.com/wp-content/uploads/2017/03/soclean2_manual_RevH.pdf.

²² *2014 SoClean 2 User Guide*, SOCLEAN, https://www.soclean.com/wp-content/uploads/2014/04/soclean2_manual_RevE.pdf.

6. Representations that SoClean Is a Sealed or “Closed-Loop” System

133. SoClean represents that the SoClean is a “closed system” and that no “activated oxygen” escapes the device.

134. This representation is false and misleading.

135. A closed-loop system is one in which ozone circulates within but does not leave the device.

136. The SoClean devices circulate ozone through the CPAP machine which is then released into the ambient air or breathed by the CPAP user.

137. SoClean has repeatedly represented across many forums that its devices are a “closed system” and/or that no “activated oxygen” escapes. For example:

- a. A “CPAP cleaning demo video” hosted on the SoClean homepage shows “activated oxygen” circulating through the CPAP machine and SoClean device, but no “activated oxygen” escaping the CPAP machine during the cleaning process.²³ See Ex. G (Marketing Materials), Figure 3. Online, the video appears next to a “Buy Now” button.
- b. A SoClean FAQ webpage represents the following: “What is the concentration of ozone inside the SoClean CPAP cleaner and sanitizer? SoClean uses enough ozone to thoroughly sanitize your CPAP equipment and by the time you open the chamber it will have decreased to 0 ppm.”²⁴
- c. The 2017 online version of the SoClean 2 User Guide states: “The SoClean

²³ SoCLEAN, <https://www.soclean.com> (last visited Apr. 21, 2019).

²⁴ *SoClean and Activated Oxygen FAQs*, SoCLEAN, <https://www.soclean.com/sleep-talk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 16, 2019).

produces activated oxygen in a closed system.”²⁵

- d. The 2014 online version of the SoClean 2 User Guide states: “Is the SoClean harmful to me or the environment? No. The activated oxygen generator is always kept at a safe level and never reaches the outside environment.”²⁶

138. SoClean has made additional false and misleading representations about the SoClean devices similar to those alleged in paragraphs 96 to 137.

139. Upon information and belief, SoClean perpetuates the falsehoods alleged in paragraphs 96 to 137 by paying or otherwise incentivizing individuals to create blog posts and online reviews repeating the falsehoods.

140. Upon information and belief, SoClean perpetuates the falsehoods alleged in paragraphs 96 to 137 by using search engine optimization services.

F. The Effect of SoClean’s False Advertising

141. The foregoing false claims deceive consumers into believing that the SoClean devices do not generate ozone, do not release ozone into the atmosphere, and are safe, healthy, and suitable for use in consumer’s bedrooms.

142. SoClean’s falsehoods have allowed it to command a ninety-percent share of the market for CPAP sanitizing/sterilization devices.

143. Because SoClean and 3B are direct competitors in the same market, SoClean’s false advertising leads consumers to purchase SoClean’s products when they would otherwise purchase 3B’s products.

144. Due to the nature of SoClean’s business, its customers all have breathing problems

²⁵ 2017 SoClean 2 User Guide, SOCLEAN, https://www.soclean.com/wp-content/uploads/2017/03/soclean2_manual_RevH.pdf.

²⁶ 2014 SoClean 2 User Guide, SOCLEAN, https://www.soclean.com/wp-content/uploads/2014/04/soclean2_manual_RevE.pdf.

for which they are receiving medical treatment in the form of CPAP therapy. In fact, CPAP users are so concerned about their health that they experience the considerable inconvenience of using a CPAP machine and wearing a CPAP face mask to sleep every night.

145. CPAP users would find the risk posed by the SoClean devices generating unsafe levels of toxic gas, which is then pumped into their CPAP machines and their bedrooms, material to their purchasing decisions.

146. In addition to the harm to 3B, SoClean's false advertising poses a threat to public health.

147. Ozone exposure at levels exceeding .05 ppm negatively affects respiratory health.

148. Epidemiologic studies suggest that those with existing breathing problem may experience adverse symptoms of ozone exposure at concentrations even lower than .05 ppm.

149. SoClean's false representations have actually deceived and harmed consumers.

CLAIMS

COUNT ONE

False Advertising – Lanham Act, 15 U.S.C. § 1125(a)

150. 3B repeats and realleges all the preceding paragraphs of this Complaint as if fully set forth herein.

151. SoClean made false and misleading statements concerning its products and/or services.

152. The deception was material in that it was likely to influence purchasing decisions.

153. SoClean competes directly with 3B's CPAP sanitizing device in the relevant market, and SoClean's false and misleading statements actually deceived or had a tendency to deceive a substantial portion of the intended audience.

154. SoClean knew that the above described advertising claims are false and/or

misleading and are likely to deceive the public.

155. As a direct and proximate result of SoClean's wrongful conduct, 3B was injured, and was likely to be injured, in terms of declining sales, lost profits, loss of goodwill, and other injuries.

156. As a direct and proximate result of its wrongful conduct, SoClean has realized profits and other benefits to which it is not entitled.

157. SoClean's acts constitute a violation of the Lanham Act and entitle 3B to recover SoClean's profits, 3B's damages, and the costs of this action pursuant to 15 U.S.C. § 1117(a).

158. Because of the circumstances of the case and SoClean's egregious conduct, 3B is entitled to have its recovery upwardly adjusted pursuant to 15 U.S.C. § 1117(a).

159. Because SoClean acted intentionally, willfully, and/or in bad faith, this an exceptional case entitling 3B to recover its reasonable attorneys' fees pursuant to 15 U.S.C. § 1117(a).

COUNT TWO
Unfair Competition – New York Common Law

160. 3B repeats and realleges the allegations set forth in Count One and paragraphs 1-149 of this Complaint, as if fully set forth herein.

161. SoClean's acts and omissions as described herein constitute unfair competition against 3B.

162. SoClean's unfair competition has harmed and is continuing to harm 3B, its business, and its goodwill.

163. In addition to monetary harm, 3B has suffered and is continuing to suffer irreparable harm as a result of SoClean's unfair competition.

COUNT THREE
Deceptive Acts and Practices, N.Y. Gen. Bus. Law § 349

164. 3B repeats and realleges the allegations set forth in paragraphs 1-149 of this Complaint as if fully set forth herein.

165. SoClean's acts and practices were deceptive and misleading in a material way.

166. SoClean set out to intentionally mislead consumers and the general public, including consumers and the public at large in New York.

167. SoClean's deceptive acts or practices threaten the public health.

168. As a direct and proximate result of SoClean's wrongful acts, 3B has been injured and incurred damages in an amount to be proven at trial.

169. SoClean acted willfully and in bad faith. Accordingly, the damages sustained by 3B as a result of the unlawful conduct alleged herein should be trebled in accordance with N.Y. Gen. Bus. Law § 349(h).

COUNT FOUR
False Advertising, N.Y. Gen. Bus. Law § 350

170. 3B repeats and realleges the allegations set forth in paragraphs 1-149 of this Complaint as if fully set forth herein.

171. SoClean's false and deceptive advertising contains materially misleading statements of fact that concern the performance of the product.

172. These advertisements were aimed at the consumer public at large.

173. SoClean's marketing has caused and is likely to cause confusion and mistake and has deceived and is likely to deceive potential customers and the general purchasing public.

174. SoClean's false and misleading statements of fact threaten the public health.

175. As a direct and proximate result of SoClean's wrongful acts, 3B has been injured

and has incurred damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, 3B prays for judgment as follows:

- (A) For an Order and Judgment which:
 - i. Preliminarily and permanently enjoins SoClean, its officers, agents, servants and employees, and all persons in active concert and participation with them, including their affiliates, from further disseminating the false and deceptive advertising claims described herein in any form or medium;
 - ii. Requires SoClean to withdraw and/or retrieve all offending advertising materials, including the labeling on the packaging for the Product, from the marketplace;
 - iii. Requires SoClean to disseminate among consumers corrective advertising to dispel the false and deceptive messages contained in the subject advertising;
- (B) For an order directing SoClean to account for, and to pay to 3B all gains, profits and advantages derived by SoClean from the above-described wrongful acts;
- (C) For an award of monetary damages sustained by 3B as a result of SoClean's unlawful conduct, in an amount to be proven at trial; and
- (D) For an order multiplying or otherwise enhancing any award under paragraphs B and C directly above because of SoClean's willful and deliberate wrongdoing described herein;
- (E) For an award of punitive damages resulting from SoClean's state law violations in an amount to be proven at trial;

- (F) For an award of the costs of this action and its reasonable attorneys' fees incurred herein by 3B as authorized by law; and
- (G) For an award of such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

3B respectfully requests a trial by jury on all claims.

DATED: April 22, 2019

Respectfully submitted,

By: /s/Michael von Klemperer

Michael von Klemperer (motion for
admission *pro hac vice* filed concurrently)

Daniel Kotchen (motion for admission *pro*
hac vice forthcoming)

Daniel Low (motion for admission *pro hac*
vice forthcoming)

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